

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANDRULIS PHARMACEUTICALS CORP.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 13-1644 (RGA)
)	
CELGENE CORPORATION,)	
)	
Defendant.)	

**CELGENE'S REPLY LETTER BRIEF TO THE HONORABLE
RICHARD G. ANDREWS REGARDING ITS REQUEST FOR LEAVE
TO FILE A MOTION FOR PARTIAL SUMMARY JUDGMENT**

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January 23, 2015

Dear Judge Andrews:

Andrulis's letter (D.I. 62) provides no basis to put off the threshold issue of prosecution history estoppel. Estoppel is a pure legal issue that is based on a public record. And as both parties' letters show, the relevant facts are not genuinely disputed: (i) Andrulis narrowed its claims from a genus ("TNF- α inhibitors") to one molecule ("thalidomide") because of enablement problems; (ii) Andrulis never regained the surrendered ground at any point in prosecution of the parent and child applications; and (iii) the surrender of all molecules but thalidomide is directly related to Andrulis's after-the-fact attempt to reclaim other molecules under the doctrine of equivalents ("DOE"). On these undisputed facts, estoppel can and should be resolved by early summary judgment.

Prosecution history estoppel is ideal for early disposition, unlike DOE. Estoppel precludes the availability of DOE. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367–68 (Fed. Cir. 2003) (en banc). It presents a question of law for the Court, not the jury. *Id.* at 1368. Summary judgment of estoppel would thus avoid litigation of the "fact intensive" issues surrounding Andrulis's allegations that lenalidomide is equivalent to thalidomide. *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 565 (D.N.J. 2004).

Andrulis proposes that estoppel be decided later with all other DOE issues. But that needlessly postpones resolution of flawed allegations that can be dealt with now. There is no reason to wait, particularly because Andrulis identifies no disputed material facts. At most, Andrulis suggests (by footnote) that expert discovery is needed, but fails to explain why expert testimony might create a genuine fact dispute. Expert testimony is not required to assess estoppel. *See Festo*, 344 F.3d at 1369 (permitting, but not requiring, a court to hear expert testimony or other extrinsic evidence). As no material facts are disputed, estoppel is ripe.

Andrulis's arguments, which are wrong, present no basis for delay of the estoppel issue. Andrulis argues that: (i) it actually challenged the enablement rejection; (ii) its narrowing amendments were only in response to a restriction requirement; and (iii) the amendments were merely tangential to its allegation that lenalidomide is equivalent to thalidomide. Andrulis's arguments lack merit, and do not raise issues precluding summary judgment:

1) Andrulis cannot dispute the presumption of surrender. The indisputable prosecution history shows that Andrulis tried—and failed—to patent claims that encompassed the alleged equivalent. The examiner rejected claims to a genus of TNF- α inhibitors (including lenalidomide) as not enabled. Andrulis canceled the genus claims and went on with claims to thalidomide. (D.I. 62, Ex. B at ANDRULIS-193.) In so doing, Andrulis surrendered all molecules other than thalidomide. *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1352 (Fed. Cir. 2004).

Andrulis notes that it re-filed the rejected genus claims in a child application, but the public record shows that Andrulis never regained the already surrendered ground. In that application, Andrulis again narrowed its claims to thalidomide and ultimately abandoned the genus claims without ever addressing the enablement rejection. The Federal Circuit has squarely held that re-filing rejected claims, without more, does not recapture subject matter surrendered in a parent application because estoppel is based on the prosecution history as a whole—here, both parent and child applications. *See Mark I Mktg. Corp. v. Donnelley & Sons Co.*, 66 F.3d 285, 291–92 (Fed. Cir. 1995); *see also Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1317

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(Fed. Cir. 2007). Andrulis does not—and cannot—point to any attempt to challenge the enablement rejection at any time in the entire prosecution history. These undisputed facts are ripe for summary judgment.

2) The full context of Andrulis’s narrowing amendments presents a legal issue. Andrulis argues that its amendments were merely responses to the restriction requirement. This presents a legal issue, and Andrulis is wrong. As a matter of law, estoppel is based on the prosecution history as a whole. *See Mark I*, 66 F.3d at 291–92. Where, as here, the full prosecution history shows that amendments address both rejections and restriction requirements, estoppel arises because the applicant “no longer sought to claim” the surrendered subject matter. *Merck & Co., Inc. v. Mylan Pharms., Inc.*, 190 F.3d 1335, 1341–42 (Fed. Cir. 1999). Andrulis’s cited authority does not hold otherwise, as *Bayer* involved a restriction requirement and election *before* any rejections arose. *Bayer AG v. Duphar Int’l Research B.V.*, 738 F.2d 1237, 1239–40 (Fed. Cir. 1984). Even so, *Bayer* acknowledges that elections may invoke estoppel in some instances. *Id.* at 1243 (stating only that elections do “not *necessarily* invoke file history estoppel”) (emphasis added). Thus, as a legal matter, Andrulis’s narrowing amendments must be considered in view of the entire prosecution history, which includes the enablement rejection.

3) Andrulis’s surrender of all molecules except thalidomide was not tangential. Andrulis argues that the amendments narrowing the claims to thalidomide were only tangential to its contention that other molecules are equivalent. This issue can also be decided now. As the indisputable prosecution history shows, Andrulis conceded that it could not patent any molecule but thalidomide when it narrowed its claims to thalidomide and it never recaptured other molecules. Where a claim is narrowed from a genus to one molecule, that amendment excludes all other molecules and is not tangential. *Glaxo*, 356 F.3d at 1352, 1357. Andrulis’s cited case, *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010), is inapposite. There, the claims were not narrowed to one molecule but to a *genus* (similar gene sequences for porcine circovirus strains (PCV-2)). Thus, the patentee was not estopped from accusing strains equivalent to representative PCV-2 strains. *Id.* at 1292; *see also Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 728–29 (D. Del. 2012) (claim narrowed to “single optical isomer” could refer only to slightly less than 100% pure compositions). Here, however, Andrulis narrowed its claims only to thalidomide, not a broader category of molecules.

If granted, Celgene’s motion will substantially streamline the issues. Celgene disagrees with Andrulis’s characterization of the status of discovery in this case. Andrulis’s 170 document requests are overbroad and redundant, imposing substantial and undue burdens on Celgene. Nonetheless, Celgene has already produced over 27,000 pages of documents and will continue its review and production on a rolling basis, consistent with the Scheduling Order. (Ex. 1 at 2.) But if Andrulis’s allegations based on Revlimid® are estopped and summary judgment on Revlimid® is granted—as Celgene’s motion will show—the scope of this case would be substantially streamlined. The Revlimid® NDA file alone contains over 8 million pages and would cost well over \$200,000 to produce, but would be entirely irrelevant if summary judgment is granted. (*Id.* at 1.) The testimony of many third-party doctors also would be irrelevant.

For all of the foregoing reasons, the Court should grant Celgene leave to file its proposed summary judgment motion of noninfringement as to Revlimid®.

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Respectfully,

/s/ Derek J. Fahnestock

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